

REMARKS

Claim Amendment

After entry of the present amendment, claims 1-4, 7, 8, 11-20 and 52 are pending in this application for the Examiner's review and consideration. Claim 12 has been amended to delete the term "acrylamide derivative polymer or copolymer." New claim 52 has been added to recite that the biocompatible carrier is a saline solution. Support for the amendment can be found in the specification, *e.g.*, at page 18, lines 1-7. Claims 5, 6, 9, 10, and 21-51 have been canceled without prejudice as these are directed to non-elected subject matter or species and have been withdrawn from consideration. Since no new matter is introduced by these amendments, Applicants respectfully request their entry into the record of the present application. Applicants also reserve the right to re-present the claims and to file divisional or other continuing applications for subject matter disclosed but not claimed in the present application.

The Double Patenting Rejections

Claims 1-4, 7, 8, and 11-20 were rejected over the claims of U.S. Patent Application No. 6,436,424 ("the '424 patent") and provisionally rejected over the pending claims of U.S. Patent Application No. 10/222,819 ("the '819 application") under the judicially created doctrine of obviousness-type double patenting for the reasons set forth on pages 3-5 of the Office Action. Applicants respectfully traverse the rejections.

The claims of the '424 patent and the '819 application are directed to an injectable composition, for dermal augmentation, wherein the composition is injectable through needles of about 30 gauge or smaller. On the contrary, the present claims recite an injectable composition for tissue bulking, wherein the composition is injectable through needles of about 18 to 26 gauge. As defined in the present specification, tissue bulking refers to non-dermal tissues, specification at page 11, lines 12-17, thus expressly excluding the subject matter of the '424 patent and the '819 application, which relates to dermal tissue, *i.e.*, the skin and related areas. In addition, one of ordinary skill in the art knows that the diameter

of needles of about 18 to 26 gauge is larger than that of needles of about 30 gauge or smaller and, therefore, materials (*e.g.*, microspheres) that could fit through needles of about 18 to 26 gauge is larger than that which could fit through needles of about 30 gauge or smaller.

In view of these distinctions, Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art, based on different compositions used for different purposes as disclosed in the '424 patent and the '819 application, to achieve the present invention. Therefore, the presently claimed invention is patentably distinct from that of the '424 patent and the '819 application.

For the forgoing reasons, Applicants respectfully submit that the obviousness-type double patenting rejections have been overcome and respectfully request their reconsideration and withdrawal.

The Rejections Under 35 U.S.C. § 112

Claims 12 and 20 were rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons set forth on pages 5 and 6 of the Office Action. Applicants respectfully submit that the rejections have been made moot or overcome by the claim amendment and argument made herein.

Claim 12 has been amended to delete the term "acrylamide derivative polymer or copolymer." Thus, the rejection of claim 12, under 35 U.S.C. § 112, second paragraph, is moot.

The Examiner has also alleged that the term "capable of" in claim 20 is not a positive limitation, but only requires the ability to so perform a function, and that it "does not constitute a limitation in any patentable sense." Office Action at page 6. Applicants respectfully disagree.

As the Examiner is aware and as clearly stated in the *Manual of Patent Examining Procedure* ("MPEP," February, 2003):

There is nothing inherently wrong with defining some part of an invention in functional term. Functional language does not, in and of itself, render a claim improper. MPEP § 2173.05(g); *see also, In re*

Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA, 1971).

Therefore, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly convey to a person of ordinary skill in the pertinent art in the context in which it is used. *MPEP* § 2173.05(g). Applicants would also like to invite the Examiner's attention to *MPEP* § 2173.05(g), wherein it is specifically stated that both the terms of "incapable of" and "capable of" have been held definite and precisely defined the claimed invention. *Id.*, citing *In re Barr*, 444 F.2d 588 (CCPA 1971) and *In re Venezia*, 530 F.2d 956 (CCPA 1976).

Applicants respectfully submit that, based on these principles, the term "capable of," as used in claim 20, does not render the claim indefinite, because the term is clearly defined in the specification, *e.g.*, at page 15, line 29 to page 16, line 5, and that a person of ordinary skill in the art would know exactly what the term fairly conveys in the context in which it is used. Therefore, the rejection of claim 20, under 35 U.S.C. § 112, second paragraph, should reconsidered and withdrawn.

The Rejection Under 35 U.S.C. § 103

Claims 1-4, 7, 8, 11-20 were rejected by the Examiner under 35 U.S.C. § 103(a) as being obvious over PCT publication WO 99/44643 to Vogel et al. ("Vogel") in view of U.S. Patent No. 5,922,025 to Hubbard ("Hubbard"). Applicants respectfully traverse this rejection.

Applicants first submit that Vogel should be removed as a prior art reference to the present invention under either 35 U.S.C. § 102 or § 103, because the inventive entity in Vogel and the present application is the same* and that Vogel was published within one year of the effective filing date of the present application. Thus, Vogel is not a prior art to the present invention. Applicants further submit that Hubbard does not obviate the claimed invention for the following reasons.

* Applicants have submitted herein a Request for Correction of Inventorship and other required documents, which adds Richard Thomas as an inventor of the present application.

Hubbard discloses an augmentation material comprising smooth rounded, substantially spherical, particles of a finely divided ceramic material. Hubbard at col. 5, lines 1-3 and lines 36-37. Hubbard does not disclose a composition for dermal augmentation that comprises biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres, as presently claimed. Hubbard further fails to disclose or suggest a composition that comprises microspheres that swell to a predetermined size after injection, much less microspheres that swell after injection up to four times their pre-injection size, as presently claimed. In fact, the finely divided ceramic particles disclosed in Hubbard are, by definition, the direct opposite of the swellable and hydrophilic characters of the microspheres required by the present invention. In addition, Applicants respectfully draw the Examiner's attention to page 10, lines 9-15 of the specification, where "microspheres" are defined as "polymer or combination of polymers made into bodies of various sizes." In other words, Hubbard is totally silent with regard to swellable, hydrophilic, and polymer, all of which are required by the presently claimed invention.

The Examiner alleges, on pages 7-8 of the Office Action, that the recited terms of "injectable through needles of about 18 to 26 gauge" and "wherein the microspheres swell to a predetermined size after injection within the non-dermal tissue of said mammal" are only recitations of intended use. Applicants respectfully disagree and submit that terms are positive recitations of both structure and property of the claimed composition. For example, the "needle gauge" recitation clearly requires that the microspheres must be within certain size range and must possess certain property such that they are injectable through the recited needles. Likewise, the "swell" recitation clearly requires that the microspheres are made of specific materials and possess specific properties so that they swell as required. In this regard, Applicants further submit that, contrary to the Examiner's contentions, the ceramic particles of Hubbard cannot swell, much less to a predetermined size. Thus Hubbard's particles cannot perform the intended use of the claimed composition.

Applicants further submit that, Hubbard not only fails to suggest the present invention, but actually teaches away from it by emphasizing the use of particles made from ceramic and aluminum materials, which cannot be swellable, hydrophilic, or a polymer, as

required by the present invention. In other words, one of ordinary skill in the art, based on the disclosure in Hubbard, *i.e.*, solid rigid particles, would look away from the direction of the present invention, *i.e.*, soft swellable microspheres.

For the foregoing reasons, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) should be withdrawn.

CONCLUSION

Applicants respectfully submit that all pending claims are now in condition for allowance, early notice of which is earnestly solicited. Should the Examiner disagree, a personal or telephonic interview is respectfully requested to resolve any remaining issues in this application.

No fee is believed to be due for the submission of this response, except the fee for the Petition for Extension of Time Submitted herein. Should any additional fee be required, however, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date August 11, 2003


Beibing Gary Zhang 47,331
(Reg. No.)

For: Anthony M. Insogna (Reg. No. 35,203)

PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, D.C. 20006
(202) 496-4400

Enclosure